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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,960	09/15/2003	Leslie S. Feinberg	030716	1119

7590 08/25/2004

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EXAMINER	
GILBERT, SAMUEL G	
ART UNIT	**PAPER NUMBER**
3736	

DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/662,960	FEINBERG, LESLIE S.	
	Examiner	Art Unit	
	Samuel G Gilbert	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-9 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-9 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 15 September 2003 is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the subject and the practitioner as the same person, as in claim 9, must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as

per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-9 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter The claimed invention fails to produce a useful, tangible, concrete result in the technological arts.

In analyzing claim 1 for patent eligible subject matter, it is useful to first answer the question "What did applicant[s] invent?" In re Abele, 214 USPQ 682 (CCPA 1982). The preamble of claim 1 characterizes the invention as an "energetic based health care method . . . ." A careful review of the disclosure reveals that the applicant's invention can best be described as a procedure or methodology by which a person suffering from disfunction may seek relief. It is clear from the scope of the disclosure and the claims that no specific technology is employed in the process. Rather, what is set forth is a rather general procedure with the stated intention of helping a person correct a dysfunction.

The invention thus understood must be analyzed under the prevailing case law. The statute itself allows for the patenting of processes. However, it has been determined in many contexts that not all processes set forth patent eligible subject matter. In other words, it must always be determined whether a particular invention ostensibly falling within one of the enumerated statutory categories is in fact something for which the patent statutes were designed. A primary test that has recently been applied is whether the invention produces a useful, concrete, tangible result. See e.g., States Street Bank & Trust Co. v. Signature Financial Group Inc., 47 USPQ2d 1596 (Fed. Cir. 1998); AT&T Corp. v. Excel Communications Inc., 50 USPQ2d 1447 (Fed. Cir. 1999). Under that test, the invention must have practical utility, it must produce an

assured result, and it must not be merely an abstraction lacking in physical substance. The invention must achieve a practical application having real world value of immediate benefit to the public.

In this case, the claimed invention does not produce a "concrete" result in the sense that it cannot be reasonably assured that dysfunction would in fact be definitively managed or that healing in any scientifically measurable way would be achieved by following the steps of the method. There is simply too much subjectivity involved because the method effectively relies on subjective criteria rather than objective standards. Actual enablement of pain management and healing is speculative and the method itself is no more than an attempt and a hoped-for result.

The claimed invention does not produce a "tangible" result in the sense that it merely manipulates abstract ideas without producing a physical transformation or conversion of the subject matter expressed in the claim so as to produce a change of character or condition in some physical object. See In re Warmerdam, 31 USPQ2d 1754 (Fed. Cir. 1994); In re Schrader, 30 USPQ2d 1445 (Fed. Cir. 1994). Except for insignificant post solution activity, stimulating, the steps of the claimed method are effectively no more than ideas and concepts that are deemed abstract in nature. Mindful of the need to focus on what the inventor did in fact invent, it is not a documentation of results (a recorded abstract idea) or the use of proven healing compositions (merely ancillary or peripheral components). Rather, the invention is a method that does not produce a physical transformation or yield a tangible result. It is effectively a manipulation of abstract ideas and is thus not statutory.

Even if it might be determined that the claimed method can be characterized as producing a useful, concrete, tangible result, to be proper subject matter for patent eligibility, any useful, concrete, tangible result must be within the useful or technological arts. See e.g., In re Musgrave, 167 USPQ 280 (CCPA 1970); In re Foster, 169 USPQ 99 (CCPA 1971). The Constitution empowers Congress to promote the useful arts. The term "useful arts" has been equated with "technological arts" in a number of decisions. See e.g., In re Waldbaum, 173 USPQ 430 (CCPA 1972). The United States Supreme Court has recognized as a constitutional limitation on the patent statutes that they are "limited to the promotion of advances in the 'useful arts.'" See, Graham v. John Deere, 148 USPQ 459, 462 (1966).

In this case, the claimed invention is not within the useful or technological arts. Rather, the invention is within the realm of the liberal arts or social sciences. This is not medical technology. At best, it must be characterized as within the healing arts. In Musgrave and Foster, the inventions were deemed to be within the technological arts. In those cases, each invention clearly involved computer or machine technology. But here, there is no substantive technology involved at all. There is no substantive technology disclosed or claimed. The providing physical stimulation is a peripheral element to the actual process and cannot reasonably convert an otherwise non-

statutory process outside the technological arts into one that is in fact within the technological arts. Compare, Diamond v. Diehr, 209 USPQ 1, 10 (1981) (insignificant post-solution activity will not transform an unpatentable principle into a patentable process; [t]o hold otherwise would allow a competent draftsman to evade the recognized limitations on the type of subject matter eligible for patent protection.) In this regard, see also, Ex parte Bowman, 61 USPQ2d 1669 (Bd. Pat. App. & Inter. 2001) (Unpublished).

Claims 1-9 do not produce a useful, concrete, tangible result in the technological arts. The invention as disclosed and claimed does not promote the progress of the useful arts. Accordingly claims 1-9 do not define statutory subject matter.

Claims 1-9 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

The utility requirement under Section 101 requires that any asserted utility be substantial, specific, and credible. Here, the asserted utility is neither. In other words, there is no real world value attributable to the claimed subject matter whereby there is provided some immediate benefit to the public. See, Nelson v. Bowler, 206 USPQ 881, 883 (CCPA 1980). The disclosure asserts utility for pain management and healing as a general goal only, and, it is more likely than not that those skilled in the medical art would doubt or question the truth of the asserted utility. No credible scientific publications or other evidence have been offered or have been uncovered that would tend to establish, more likely than not, that the utility asserted would in fact be achieved. It is not logical, scientifically or technologically, that the steps of the method claimed would be the actual cause of either pain management or healing.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as directed to subject matter not described in such a way as to enable one skilled in the art to use the invention. Because the invention lacks a substantial, specific, and credible utility as set

forth above, one skilled in the art clearly would not know how to use the claimed invention without undue experimentation. See MPEP 2107.01, IV.

Realizing that an applicant's disclosure enjoys a certain presumption of enablement, an analysis of the so-called Wands factors (MPEP 2164.01, 2164.01(a); In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988)) rebuts the presumption. The nature of the invention is one that immediately suggests a speculative rather than a documented scientific endeavor. The prior art does not present any credible scientific evidence of related processes achieving the asserted result. There is virtually no reliable predictability as to outcome based on such a method. The particular direction given by the inventor to achieve the result is general and widely alternative in nature. There are no actual scientifically conducted working examples of the process achieving the asserted results. The quantity of experimentation necessary to use the invention to the end stated looms large given the speculative nature of the invention. Accordingly, enablement is not established by the disclosure sufficient to meet the "more likely than not" standard.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 and 8 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Omura (5,188,107).

Omura teaches using muscle response testing (other than conscious to other than conscious level). Omura does not specifically set forth forming a pathway statement, and interrogating the subject, it is the examiner's position that in performing the method as disclosed by Omura the practitioner would inherently form a pathway

statement and interrogate the patient before performing the bi-digital o-ring test as the patient is tested for different organs or cancers as described in the specification. To help the patient understand the testing such an explanation must be presented when switching between test slides as described. The examiner is taking the interaction between the patient and practitioner as a semantic algorithm.

Claims 1-9 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by 6 pages from www.neuromodulationtechnique.com, by Leslie S Feinberg D.C.. The web pages have been archived to 08/31/2002, see webpage from internet archive wayback machine.

1.105 Requirements for information.

(1) In the course of examining or treating a matter in a pending or abandoned application filed under 35 U.S.C. 111 or 371 (including a reissue application), in a patent, or in a reexamination proceeding, the examiner or other Office employee may require the submission, from individuals identified under § 1.56(c), or any assignee, of such information as may be reasonably necessary to properly examine or treat the matter, for example:

(i) Commercial databases : The existence of any particularly relevant commercial database known to any of the inventors that could be searched for a particular aspect of the invention.

(ii) Search : Whether a search of the prior art was made, and if so, what

was searched.

(iii) Related information : A copy of any non-patent literature, published application, or patent (U.S. or foreign), by any of the inventors, that relates to the claimed invention.

(iv) Information used to draft application : A copy of any non-patent literature, published application, or patent (U.S. or foreign) that was used to draft the application.

(v) Information used in invention process : A copy of any non-patent literature, published application, or patent (U.S. or foreign) that was used in the invention process, such as by designing around or providing a solution to accomplish an invention result.

(vi) Improvements : Where the claimed invention is an improvement, identification of what is being improved.

(vii) In Use : Identification of any use of the claimed invention known to any of the inventors at the time the application was filed notwithstanding the date of the use.

(2) Where an assignee has asserted its right to prosecute pursuant to § 3.71(a) of this chapter, matters such as paragraphs (a)(1)(i), (iii), and (vii) of this section may also be applied to such assignee.

(3) Any reply that states that the information required to be submitted is unknown and/or is not readily available to the party or parties from which it was requested will be accepted as a complete reply.

(b) The requirement for information of paragraph (a)(1) of this section may be included in an Office action, or sent separately.

(c) A reply, or a failure to reply, to a requirement for information under this section will be governed by §§ 1.135 and 1.136.

[Removed and reserved, 62 FR 53131, Oct. 10, 1997, effective Dec.1, 1997; added, 65 FR 54604, Sept. 8, 2000, effective Nov. 7, 2000

The examiner hereby requests the following information:

As of 08/31/2002 (more than a year prior to applicants filing date) the inventor had a website where seminars were promoted. The examiner would like the following information provided, When these seminars took place; Was the a fee charged for these seminars; and What was disclosed at these seminars?

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Patents 5,913,835; 5720,304; and 5,579,783 teach medical diagnostic methods and devices.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel G Gilbert whose telephone number is 703-308-3553. The examiner can normally be reached on M-F 5:30-2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Beth Jones can be reached on 703-308-3400. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Samuel G Gilbert
Primary Examiner
Art Unit 3736

sgg